# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Birp Oral Emulsion for Cattle

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

| Qualitative composition | Quantitative composition % w/v |
|---|---|
| Simethicone | 1.00 |
| **Excipients** | |
| Sodium propyl hydroxybenzoate | 0.05 |
| Sodium methyl hydroxybenzoate | 0.15 |

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Oral emulsion.
A white emulsion of Simethicone.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Cattle.

### 4.2 Indications for use, specifying the target species

For the relief of gaseous and frothy bloat in cattle.

### 4.3 Contraindications

None known.

### 4.4 Special warnings for each target species

Secondary or free-gas bloat most often occurs in single animals, in which there is obstruction of eructation. In such cases, treatment should be supported by veterinary diagnosis of the cause of the failure of eructation. In outbreaks of primary frothy bloat, management strategies should be introduced to reduce foam production in the rumen or to control access of cattle to pasture or grains that promote excess gaseous foams.

## 4.5 Special precautions for use

i. Special precautions for use in animals

Use the container on one occasion only; discard it and any remaining contents after use.

ii. Special precautions for the person administering the veterinary medicinal product to animals

Wash hands after use.

## 4.6 Adverse reactions (frequency and seriousness)

None known.

## 4.7 Use during pregnancy, lactation or lay

No special precautions.

## 4.8 Interaction with other medicinal products and other forms of interaction

None known.

## 4.9 Amount(s) to be administered and administration route

By oral administration, 50 to 100 ml. A second dose may be given 3 hours later if required.

## 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not known.

## 4.11 Withdrawal period(s)

Meat: Zero days
Milk: Zero hours

# 5. PHARMACOLOGICAL PROPERTIES

### Pharmacotherapeutic group

Other alimentary tract and metabolism products, other alimentary tract and metabolism products for veterinary use, Drugs for treatment of acetonemia

### ATC Vet Code

QA16Q

### 5.1 Pharmacodynamic properties

The product is not pharmacologically active, and acts locally in the rumen of cattle by changing the surface tension of small gas bubbles trapped in foam, causing them to coalesce.
Simethicone (activated dimethicone, activated polymethylsiloxane) is used widely in the treatment of flatulence and for the elimination of gas or air foam from the gastrointestinal tract in man.

### 5.2 Pharmacokinetic properties

Simethicone is not absorbed following oral administration. Physiologically, silicones are extremely inert. It is considered to be non-toxic.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium propyl hydroxybenzoate
Sodium methyl hydroxybenzoate
Glycerol monostearate (self emulsifying)
Dilute hydrochloric acid (for pH adjustment)
Water, purified

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

### 6.4 Special precautions for storage

Shake the bottle before use.
Do not store above 25$^{o}$C.
Do not freeze.

### 6.5 Nature and composition of immediate packaging

100 ml, low density, opaque, polyethylene bottle with a black, urea formaldehyde R6/22 mm cap, with an expanding polyethylene wad.

### 6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

## 8. MARKETING AUTHORISATION NUMBER

Vm 36408/4016

## 9. DATE OF FIRST AUTHORISATION

30 March 1994

## 10. DATE OF REVISION OF THE TEXT

August 2021

Approved 18 August 2021